



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,518	02/12/2004	Edward Roydon Jost-Price	50164/033002	6397

21559 7590 01/22/2009
CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110

EXAMINER

KIM, JENNIFER M

ART UNIT	PAPER NUMBER
----------	--------------

1617

NOTIFICATION DATE	DELIVERY MODE
-------------------	---------------

01/22/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

Office Action Summary	Application No. 10/777,518	Applicant(s) JOST-PRICE ET AL.	
	Examiner JENNIFER MYONG M. KIM	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on June 30, 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) 4, 5, 8-14, 16-21, 23-27, 30-56 and 61 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6, 7, 15, 22, 28, 29 and 57-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The reply filed June 30, 2008 have been received and entered into the application.

Applicant's arguments with respect to claims 1-3, 6, 7, 15, 22, 28, 29 and 57-60 have been considered but are moot in view of the new ground(s) of rejection.

It is noted that claims 1-3, 6, 7, 15, 22, 28, 29 and 57-60 have been examined only to the extent of applicants' election, that is **cyclosporin A** as a species of NsIDI, **sertraline** as a species of NsIDI enhancer, and **epinephrine** as a species of the third agent.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 6, 7, 29 and 57-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hashimoto et al. (1998) and Am Ende et al. (U.S. Patent No. 6,517,866 B1).

Hashimoto et al. teach that cyclosporine therapy is effective in the treatment of psoriasis. Hashimoto et al. concluded that cyclosporine treatment is an effective and safe treatment to maintain improved conditions of psoriasis. (abstract).

Am Ende et al. teach that sertraline is effective for the treatment of inflammatory disorders such as psoriasis. (column 10 line 66-column 11 line 3, column 12 line 25-30 and column 13, lines 60-65).

The claims differ from the cited references in claiming combination of cyclosporin and sertraline to treat psoriasis. To employ combinations of sertraline and cyclosporin to treat psoriasis would have been obvious because all the components are well known individually for treating psoriasis. It would be expected that the combination of

components would treat psoriasis as well. One of ordinary skill in the art would have combined the anti-psoriasis agents by known methods and that in combination, each element merely would have performed the same antipsoriasis activity as it did separately. The convenience of putting the compounds having the same antipsoriasis activity of cyclosporin and sertraline together in one dosage form, though perhaps a matter of great convenience does not produce a "new" or "different" function and to those skilled in the art, the use of the old elements in combination would have been obvious. The motivation for combining the components flows from their individually known common utility (see *In re Kerkhoven*, 205 USPQ 1069(CCPA 1980)).

Regarding the kit of instant claims 57-60, it is a standard of practice in the pharmaceutical arts to enclose a composition in a vessel, and to enclose instructions for use in a package. As for the written instructions, it cannot impart patentable difference because it cannot distinguish the invention from the obvious combination of the prior art in terms of patentability. Regarding the claimed route of administration set forth in claim 28, such is obvious because the dermatological conditions such as psoriasis are often treated topically. One of ordinary skill in the art would optimize the route of administration for the obvious combination for the topical administration in order to provide most direct site of action for the treating dermatological condition such as psoriasis, which is often treated topically. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Claims 15, 22 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hashimoto et al. (1998) and Am Ende et al. (U.S. Patent No. 6,517,866 B1) as applied to claims 1-3, 6, 7, 29 and 57-60 above and further in view of Deckers et al. (U.S. Patent No. 6,372,234 B1).

The teaching of Hashimoto et al. and Am Ende et al. as applied as before.

Neither Hashimoto et al. nor Am Ende et al. teach the employment of epinephrine.

Deckers et al. teach that epinephrine is a known anti-psoriasis active. (column 21, lines 7-15).

To combine epinephrine in the obvious combinations of sertraline and cyclosporin as modified by Hashimoto et al. and Am Ende et al. to treat psoriasis would have been obvious because epinephrine is also well known in the art for treating psoriasis in view of Deckers et al. It would be expected that the combination of all components would treat psoriasis as well. One of ordinary skill in the art would have combined the anti-psoriasis agents by known methods and that in combination, each element merely would have performed the same antipsoriasis activity as it did separately. The convenience of putting the compounds having the same antipsoriasis activity of epinephrine, cyclosporin and sertraline together in one dosage form, though perhaps a matter of great convenience does not produce a "new" or "different" function and to those skilled in the art, the use of the old elements in combination would have been obvious. The motivation for combining the components flows from their

individually known common utility (see *In re Kerkhoven*, 205 USPQ 1069(CCPA 1980)). Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

None of the claims are allowed.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER M. KIM whose telephone number is (571)272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JENNIFER M KIM/
Primary Examiner, Art Unit 1617

Jmk
January 15, 2009